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O'Shea Getz P.C. 1500 MAIN ST. SUITE 912 SPRINGFIELD, MA 01115				
EXAMINER				
DOE, SHANTA G				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/509,040

## Applicant(s)

LEHMANN ET AL.

## Examiner

SHANTA G. DOE

## Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/003)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/2009 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed 6/29/2009 have been fully considered but they are not persuasive. The applicant's argument regarding claim 1 was not found persuasive, specifically the argument stating that a prima facie case of obviousness has not been established because the examiner stated "it was known in the art at the time to do so". The examiner respectfully disagrees with the applicant argument because the Duveneck reference does disclose a source of a fluid being fluidly connected to an inlet of a device. However, the reference did not specifically show the source being physically connected to the inlet hence the examiner used the Rokugawa reference to shown that it is well known in the art to have the sources be physically connected to an inlet, connecting a source of a fluid to an inlet is not new/novel and it would have been obvious to one having ordinary skill in the art at the time of the invention to do so. Additionally, applicant's argument that if the Rokugawa reference is combined with

Duveneck then Duveneck no longer works for its intended purpose was not found persuasive because the Rokugawa reference was used to show that a fluid source can be physically connected to an inlet and Duveneck already showed that the source is fluidly connect to the inlet, hence the examiner disagrees that modifying the Duveneck reference to have the source physically connected to the inlet renders the Duveneck no longer suitable for its intended purpose. Furthermore, applicant's argument that Sieben teaches away from the Duveneck reference because Sieben explicitly teaches away from using an optical window such as coupling-grating whilst Duveneck discloses an optical window such as the coupling-in grating was not found persuasive because the Sieben reference was used to show that it is known in the art to use a carrier element comprising a semi-conductive device with the surface prepared for coupling cells thereto because of the added benefit as was stated in the rejection of claim 18 in the office action dated 1/29/2009 and the Sieben reference was not used to modify the optical window of Duveneck. The applicant's argument drawn to the "metabolically-influencing cell excitation reservoir is directed to the newly amended claim 18, see art rejections below.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duveneck (US 6,469,785) in view of Rokugawa (US 4,621,059).

Regarding claim 1, Duveneck disclose a device for detecting a luminescence event in, at, or in the immediate vicinity of a cell, a cell cluster, or a tissue, said device

comprising: having

- (a) a carrier element (76) with a surface (7) prepared for direct or indirect coupling of cells,
- (b) a detector (detection unit 4 in the form of a photodiode) for receiving a luminescence signal indicative of the luminescent event, where the detector is integrated into the carrier element below surface,
- (c) a cover (2) covering surface covering the prepared surface to form a cavity(68), the cover having an inlet opening(64) and an outlet opening(66), and
- (d) an fluid source fluidly connected to an inlet opening (64).(see Duveneck fig 1 and 8, col. 5 lines 13- 27, 53-58 line65 - col. 6 line 14, col. 6 lines 48 - lines 67; col. 7 lines 5 - 12, col. 8 lines 26 - 38, col. 17 lines 59 - 67, col. 19 lines 25 -59, col. 21 lines 10 - 14, lines 42 - 56 and col. 22 lines 15-20). However, Duveneck fails to disclose that the source is a reservoir .

Rokugawa (US 4,621,059) discloses a device for detecting luminescence where in an excitation source (12) is a reservoir connected to an the inlet opening (see Rokugawa fig 1 col. 2 lines 17 - 28, col. 3 lines 21 - col. 4 line 68).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have the source of the fluid be a reservoir connected to the inlet opening of the device of Duveneck as taught by Rokugawa since a reservoir is a functionally equivalent means known in the art for containing a liquid to be supplied to an inlet.

Additionally, the phrase "and containing a biological or chemical excitation medium that includes a luminophore, where the excitation medium influences the metabolism of the cell during excitation thereof...the luminescence signal" is intended use of the reservoir and the phrase does not further limit the claim. Additionally the reservoir as disclosed by the prior is capable of the applicant's stated intended use.

Regarding claim 2, the combined reference as applied to claim 1 above discloses the device according to claim 1 in which a optical filter (636) is located between prepared surface (609) and the optical detector (604) (see Duveneck col. 16 lines 46 - 62).

Regarding claim 4, the combined reference as applied to claim 1 discloses the device of claim 1, in which multiple detectors are integrated into carrier element below the surface prepared for coupling the cells (see Duveneck fig. 1(detection unit could be an array of detector) fig 5, col. 5 lines 53 - 56; col. 6 lines 48 - 49; col. 13 lines 21 - 31)

Regarding claim 5, the combined reference as applied to claim 4, disclose the device according to claim 4, in which detector comprises a photodiode (see Duveneck col. 6 lines 48 - 49).

Regarding claim 6, the combined reference as applied to claim 1 discloses device according to claim 1, comprising an evaluation circuit (circuits for driving the photoelectric detectors (detector which detects light / luminescence intensity and

converts it into corresponding electrical signals and a measurement of the activity on the sensing surface is obtained or evaluated) connected to at least one detector (see Duveneck col. 3 lines 42 - 44 and lines 50 -52).

Regarding claim 7, the combined reference as applied to claim 6 above discloses the device of claim 6, in which the evaluation circuit is integrated into the carrier element (the circuit for driving the detector are produces on the same substrate (carrier); see Duveneck col. 3 lines 42 - 44 and lines 50 -52).

Regarding claim 8, the combined reference as applied to claim 6 above discloses the device of claim 6. The combined reference fails to disclose the device of claim 6 in which the excitation reservoir is controlled by the evaluation circuit to send the chemical or biological substance to the inlet opening (8).

Rokugawa (US 4,621,059) further discloses a biosensor having a reservoir (12) controlled by a circuit (control valve (8)) to send substance from the source (12) to an inlet opening (see Rokugawa fig., col. 3 lines 20 -23).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have the excitation source be controlled by the circuit of the combined reference as taught by Rokugawa in order to make dispensing of substance from the source automated and further more since, it was well known in the art at the time to have a source be controlled by a circuit.



Regarding claim 9, the combined reference as applied to claim 8 discloses the device according to claim 8. The combined reference fails to disclose the device of claim 8, in which a valve is disposed in an inlet line between the reservoir and inlet opening to control the supply of medium.

Rokugawa (US 4,621,059) further discloses a biosensor having a reservoir(12), a control valve (8) disposed between the source (12) and the inlet (see Rokugawa fig., col. 3 lines 20 -23).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have a valve disposed between the inlet and the source of the combined reference as taught by Rokugawa, since, Rokugawa states on lines 22 -23 that such a modification would aid in the regulation of the quantity of the substance from the source that is added/dispensed to the inlet.

Regarding claim 10, the combined reference as applied to claim 1 above discloses the device according to claim 1, wherein an adhesion matrix (adhesion promoting layer is applied to a waveguide surface) and/or a growth substrate for cells is applied to the surface (see Duveneck col. 18 lines 50 - 52).

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duveneck (US 6,469,785) in view of Rokugawa (US 4,621,059) as applied to claim 1 above, and further in view of Sieben et al (US 6,104,495).

Regarding claim 3, the combined reference as applied to claim 1 above discloses the device of claim 1. However, the combined reference fails to disclose the device of claim 1 in which the carrier element is a semiconductor body. Sieben et al (US 6,104,495) discloses a device for detecting signals related to chemical or physiological condition in cells immobilized on a sensing surface attached to semiconductor body (semiconductor material) carrier (see Sieben abs, col. 1 line 53 - col. 2 line 7; col. 3 lines 8 - 24). It would have been obvious to one having ordinary skill in the art at the time of the invention to use a semiconductor body as the carrier element in the device of the combined reference as taught by Sieben, since, Sieben states at col. 3 lines 11-13 that such a modification would allow for the use of conventional fabrication processes for integrated circuit on the carrier.

7. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duveneck (US 6,469,785) in view of Rokugawa (US 4,621,059) as applied to claim 1, and further in view of Schurmann-Mader et al (WO 2001/043875) .

Regarding claim 12, the combined references disclose the device according to claim 1 in which an immobilizing medium (8) is applied to the surface (7). However, the combined references fail to specifically teach that a cell-immobilizing medium is applied to surface. Schurmann-Mader (see US 2002/0182631 for English language equivalent) discloses that it is known in the art to apply cell-immobilizing medium to a sensing

surface (a layer is deposited on the surface (base plate) for the immobilization of biological recognition elements such as whole cells or fragments of cells) (see the US equivalent case (US 2002/0182631) of Schurmann-Mader paragraph [0052] and [0054]). It would have been obvious to one having ordinary skill in the art at the time to have an immobilizing medium be a cell immobilizing medium as taught by Schurmann-Mader since it was known in the art at the time to use such immobilizing medium on a sensing surface.

Regarding claim 14, the combined references as applied to claim 1 above, disclose the device according to claim 1 wherein chemical or biochemical recognition elements are immobilized on the sensing surface. However, the combined references fail to disclose the device of claim 1 wherein at least one cell (6) is immobilized at the surface.

Schurmann-Mader discloses that it is known in the art to immobilize biological or biochemical recognition elements such as whole cells on sensing surfaces (see US equivalent case (US 2002/0182631) of Schurmann-Mader paragraph [0054]). It would have been obvious to one having ordinary skill in the art at the time of the invention to immobilize at least one cell on the surface of the combined references as taught by Schurmann-Mader since it was well known in the art at the time of the invention to do so.

8. Claims 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Duveneck (US 6,469,785) in view of Rokugawa (US 4,621,059) as applied to claim 1 and 10 above, and further in view of Parce et al (5,278,048).

Regarding claim 11, the combined references as applied to claim 10 above, disclose the device according to claim 10. However, the combined references fail to disclose the device of claim 10 in which the growth substrate comprises gelatin. Parce (5,278,048) discloses a detecting/sensing device in which non-adherent cells may be grown on the surface of the sensor by mixing the cell with gelatin and then applying the mixture to the surface of the silicon sensor. It would have been obvious to one having ordinary skill in the art at the time of the invention to include a substrate such as gelatin in the device of the combined references as taught by Parce, since Parce states such substrates aid in adhesion of living cells to the sensing chamber and cells can be grown on such substrate (see col. 5 line s 60-co1.6 lines 11)

Regarding claim 15, the combined references as applied to claim 1 disclose the device according to claim 1. However, the combined reference fail to disclose the device of claim 1 in which a depression is created in the surface of the carrier device prepared for receiving cells, by contrast with surface areas (101) not prepared for receiving cells, said depression being preferably at least 100 nm deep. Parce (5,278,048) discloses a detecting/sensing device in which a flow chamber has a surface with plurality of wells or depression. It would have been obvious to one having ordinary skill in the art at the time of the invention to create depressions on carrier surface of the combined references

device as taught by Parce since Parce states at col. 2 lines 41-43 that such a modification would act to physically trap the living cell onto the surface by gravitational sedimentation. Further more, Parce discloses that the wells/depression should be of a sufficient width and depth to enable cells to remain in the chamber during ordinary flow rates (Parce col. 2 lines 44 - 46). It would have been obvious to one having ordinary skill in the art at the time of the invention to have the depressions be at least 100 nm deep, since it has been held that were the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duveneck (US 6,469,785) in view of Rokugawa (US 4,621,059) and Schurmann-Mader et al (WO 2001/043875) as applied to claim 12 above, and further in view of Ikeda et al (US 5,582,697).

Regarding claim 13, the combined references as applied to claim 12 disclose the device according to claim 12. However, the combined references fail to disclose the device of claim 12 in which the medium comprises negatively charged polystyrene. Ikeda (US 5,582,697) discloses that it is known in the art to use negatively charged polystyrene (polystyrene sulfonate) as an immobilization medium. It would have been obvious to one having ordinary skill in the art at the time of the invention to use negatively charge

polystyrene as the immobilizing medium as taught by Ikeda since is known in the art for its hydrophilic properties.

10. Claims 18, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duveneck (US 6,469,785) in view of Sieben et al (US 6,104,495).

Regarding 18 and 22, Duveneck does disclose a device for detecting a cellular metabolic process associated with a cell by detecting a luminescence event in, at, or in the immediate vicinity of the cell, the device comprising: an immobilized surface or prepared surface, a detector for providing a luminescence signal indicative of the luminescent event, where the detector is integrated into the device below the cell; a cover that covers the prepared surface to form a cavity, the cover having an inlet and an outlet; an excitation source that provides to the cavity via the inlet a biological or chemical excitation medium that includes a luminophore and a housing that in cooperation with the prepared surface forms a cavity having inlet and outlet. (see Duveneck fig 1 and 8, col. 5 lines 13- 27, 53-58 line 65 - col. 6 line 14, col. 6 lines 48 - lines 67; col. 7 lines 5 -12, col. 8 lines 26 - 38, col. 17 lines 59 - 67, col. 19 lines 25 -59, col. 21 lines 10 - 14, lines 42 - 56 and col. 22 lines 15-20).

The Duveneck reference fails to disclose that the device comprises a semiconductive device with the surface prepared for coupling the cell thereto. Additionally, the Duveneck fails to specifically disclose that the source is a reservoir.

Sieben et al (US 6,104,495) discloses a device for detecting signals related to chemical or physiological condition in cells immobilized on a sensing surface attached to semiconductor body (semiconductor material) carrier (see Sieben abs, col. 1 line 53 - col. 2 line 7; col. 3 lines 8 - 24).

It would have been obvious to one having ordinary skill in the art at the time of the invention to use a semiconductor body as the carrier element in the device of the Duveneck reference as taught by Sieben, since, Sieben states at col. 3 lines 11-13 that such a modification would allow for the use of conventional fabrication processes for integrated circuit on the carrier.

Rokugawa (US 4,621,059) discloses a device for detecting luminescence where in the excitation source (12) is a reservoir connected to an the inlet opening (see Rokugawa fig 1 col. 2 lines 17 - 28, col. 3 lines 21 - col. 4 line 68).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have the source of the fluid be a reservoir in the device of Duveneck as taught by Rokugawa since a reservoir is a functionally equivalent means known in the art for containing a liquid to be supply to an inlet.

The above phrase "excitation medium influences the metabolism of the cell during excitation thereof by the medium, and where the luminophore reacts with a

metabolic product of the cell during the excitation thereof to provide luminescence detected by the detector” is an intended use and does not further limit the claim.

Regarding claim 19, the combined references disclose the device of claim 18, further comprising an optical filter located between the prepared surface and the optical detector, and where a plurality of optical detectors are integrated into the semiconductive substrate below the prepared surface (see Duveneck fig 1 and 8, col. 5 lines 13- 27, 53-58 line 65 - col. 6 line 14, col. 6 lines 48 - lines 67; col. 7 lines 5 -12, col. 8 lines 26 - 38, col. 17 lines 59 - 67, col. 19 lines 25 -59, col. 21 lines 10 - 14, lines 42 - 56 and col. 22 lines 15-20) .

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duveneck (US 6,469,785) in view of Sieben et al (US 6,104,495) as applied to claim 18 above, and further in view of Rokugawa (US 4,621,059).

Regarding claim 20, the combined references of Duveneck and Sieben disclose the device of claim 18. The combined references fail to disclose the device of claim 18 in which the excitation reservoir is controlled by the evaluation circuit to send the chemical or biological substance to the inlet opening (8).

Rokugawa (US 4,621,059) further discloses a biosensor having a source (12) controlled by a circuit (control valve (8)) to send substance from the source (12) to an inlet opening (see Rokugawa fig., col. 3 lines 20 -23).



It would have been obvious to one having ordinary skill in the art at the time of the invention to have the excitation source be controlled by the circuit of the combined reference as taught by Rokugawa in order to make dispensing of substance from the source automated and further more since, it was well known in the art at the time to have a source be controlled by a circuit.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duveneck (US 6,469,785) in view of in view of Sieben et al (US 6,104,495) as applied to claim 18, and further in view of Schurmann-Mader et al (WO 2001/043875).

Regarding claim 21, the combined references of Duveneck and Sieben disclose the device according to claim 18 in which an immobilizing medium (8) is applied to the surface (7). However, the combined reference fails to specifically teach that a cell-immobilizing medium is applied to surface.

Schurmann-Mader (WO 2001/043875) discloses that it is known in the art to apply cell-immobilizing medium to a sensing surface (a layer is deposited on the surface (base plate) for the immobilization of biological recognition elements such a whole cells or fragment of cells) (see the equivalent US Schurmann-Mader case (US 2002/0182631) paragraph [0052] and [0054] for English translation of WO).

It would have been obvious to having ordinary skill in the art at the to have a immobilizing medium be a cell immobilizing medium as taught by Schurmann-Mader,

since it was known in the art at the time to use such immobilizing medium on a sensing surface.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter D. Griffin/  
Supervisory Patent Examiner,  
Art Unit 1797